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RESEARCH ARTICLE

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The effectiveness and cost-effectiveness of strength and balance Exergames to reduce falls risk for people aged 55 years and older in UK assisted living facilities: a multi-centre, cluster randomised controlled trial

Emma K. Stanmore^{1,2,3*} , Alexandra Mavroeidi¹⁰, Lex D. de Jong^{4,5}, Dawn A. Skelton¹⁰, Chris J. Sutton^{3,6}, Valerio Benedetto⁷, Luke A. Munford⁸, Wytse Meekes⁹, Vicky Bell¹ and Chris Todd^{1,2,3}

Abstract

Background: Falls are the leading cause of fatal and non-fatal unintentional injuries in older people. The use of Exergames (active, gamified video-based exercises) is a possible innovative, community-based approach. This study aimed to determine the effectiveness of a tailored OTAGO/FaME-based strength and balance Exergame programme for improving balance, maintaining function and reducing falls risk in older people.

Methods: A two-arm cluster randomised controlled trial recruiting adults aged 55 years and older living in 18 assisted living (sheltered housing) facilities (clusters) in the UK. Standard care (physiotherapy advice and leaflet) was compared to a tailored 12-week strength and balance Exergame programme, supported by physiotherapists or trained assistants. Complete case analysis (intention-to-treat) was used to compare the Berg Balance Scale (BBS) at baseline and at 12 weeks. Secondary outcomes included fear of falling, mobility, fall risk, pain, mood, fatigue, cognition, healthcare utilisation and health-related quality of life, and self-reported physical activity and falls.

Results: Eighteen clusters were randomised (9 to each arm) with 56 participants allocated to the intervention and 50 to the control (78% female, mean age 78 years). Fourteen participants withdrew over the 12 weeks (both arms), mainly for ill health. There was an adjusted mean improvement in balance (BBS) of 6.2 (95% CI 2.4 to 10.0) and reduced fear of falling ($p = 0.007$) and pain ($p = 0.02$) in the Exergame group. Mean attendance at sessions was 69% (mean exercising time of 33 min/week). Twenty-four percent of the control group and 20% of the Exergame group fell over the trial period. The change in fall rates significantly favoured the intervention (incident rate ratio 0.31 (95% CI 0.16 to 0.62, $p = 0.001$)). The point estimate of the incremental cost-effectiveness ratio (ICER) was £15,209.80 per quality-adjusted life year (QALY). Using 10,000 bootstrap replications, at the lower bound of the NICE threshold of £20,000 per QALY, there was a 61% probability of Exergames being cost-effective, rising to 73% at the upper bound of £30,000 per QALY.

Conclusions: Exergames, as delivered in this trial, improve balance, pain and fear of falling and are a cost-effective fall prevention strategy in assisted living facilities for people aged 55 years or older.

Trial registration: The trial was registered at ClinicalTrials.gov on 18 Dec 2015 with reference number [NCT02634736](https://clinicaltrials.gov/ct2/show/study/NCT02634736).

* Correspondence: emma.k.stanmore@manchester.ac.uk

¹Division of Nursing, Midwifery and Social Work, School of Health Sciences, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester M13 9PL, UK

²Manchester Academic Health Science Centre, Core Technology Facility, The University of Manchester, 46 Grafton Street, Manchester M13 9NT, UK

Full list of author information is available at the end of the article



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Background

Fall-related injuries are the largest cause of accidental death in older people across Europe [1] and the second leading cause of accidental death amongst older people globally [2]. Over 30% of community-dwelling people aged 65 and older and 50% of people aged 80 and over fall at least once per year [3, 4]. People living in retirement villages/assisted living facilities fall frequently [5]. Those identified as frail fall more frequently than those who are classified as vigorous [6, 7]. Falls are associated with admission to residential care homes, reduced functioning, psychological problems such as fear of falling and loss of confidence leading to social isolation and increased dependency. The direct and indirect costs of falls are substantial, for example, estimated costs in the UK NHS are in excess of £2.3 billion per year [8].

There is strong evidence that strength and balance-based exercises reduce falls by up to 42% [3, 9, 10] and that strength and balance exercise as a stand-alone intervention may be the most cost-effective approach to fall prevention at a population level [11]. Although there are few studies in assisted living facilities, a cluster randomised controlled trial of group strength and balance exercise in retirement villages in Australia showed a reduction of 22% falls in the intervention group compared to the control [5]. Exercise as a means of fall prevention and for the promotion of independence has been welcomed by older people, as a positive step that individuals can take for themselves [12]. Reviews of community-based fall prevention indicates that strength and balance exercise need to be tailored, progressive and of adequate dose (50 h) [3, 13, 14]. Sherrington et al. reveal that exercise programmes that are of a higher dose (more than 3 h/week) have larger effects [14]. Such training can be costly and inaccessible to older adults [15]. The repetitive nature of these exercises may also discourage older adults to exercise in the home setting, thereby rendering the intervention ineffective [16]. Uptake and adherence to exercise programmes is low, and appropriate levels and progression are often not adequately prescribed [5, 17]. Fear of falling can lead to restriction or avoidance of daily activities, loss of independence, depression and a reduction in quality of life [18]. In frailer older adults and for those living in institutional settings, there is also the risk that unsupervised exercise can increase risk of falls [16, 19]. A number of reviews of exercise to improve function in frailer older adults recommend supervision to ensure progression and effectiveness [20, 21]. Thus, there are compelling reasons to find interventions that are both effective and safe for this population.

Exergaming (active video games which combine gameplay with physical exercise and may also incorporate types of virtual reality simulations) may be a feasible tool for older people to improve exercise uptake, challenge and progression [22]. There is growing evidence that

Exergaming may also improve function and adherence and provide other health outcomes [4, 23] and that such technology-based approaches can be attractive to older people [24]. The advantages of using gaming systems to deliver exercise are that they can be immersive, entertaining and enjoyable, potentially improving adherence and frequency/duration of the exercise programme [25, 26]. The gamified elements of Exergames (levels, points, progress) may also encourage uptake and adherence to exercise [27, 28]. The feedback on progress alongside comparison or competition with other players may be persuasive and motivate longer-term use [29, 30]. A recent meta-analysis of effectiveness of virtual reality (VR) games for fall prevention in older people found positive effects on balance and fear of falling compared with no intervention; VR games were also concluded to be superior to conventional treatment [31]. But a high risk of bias, small sample sizes and large variability between methods and interventions mean evidence remains inconclusive and further research is needed. Other systematic reviews of virtual reality exercise programmes, Exergames and technology-based exercise interventions for older people [32–34] present similar conclusions that these interventions have potential, but larger and more rigorous studies are required to make more definitive conclusions regarding the effectiveness of Exergames to improve outcomes such as fall rate and fall risk.

The development and design of the Exergames used in this study were previously tested in a feasibility study [25, 35]. We followed the UK Medical Research Council (MRC) Guidance for Developing and Evaluating Complex Interventions [36] that recommends: identifying the evidence base and relevant theory; modelling process and outcomes; and then testing through feasibility or pilot studies prior to a full-scale evaluation [36].

Exergame programmes were planned to be carried out on a one-to-one basis (i.e. one person playing the Exergames at a time, supervised for research purposes by a physiotherapist or a physiotherapist assistant) either as part of a group setting or individually. Tailoring the Exergame programme and setting realistic, person-centred goals that are continuously reassessed to ensure personalisation and progression were also deemed important [37–39]. Understanding the health benefits of exercise and having self-belief in one's ability to exercise (self-efficacy) are also necessary [41, 42]. There are also practical considerations for the delivery of the intervention such as ease of access to the exercise, particularly for frailer older adults unwilling or unable to travel [15, 43].

This trial investigated the effectiveness of a suite of Exergames that were developed with, and for, older people to improve function and reduce the risk of falls [25]. A series of games were co-created with older adults, therapists and software designers [25], which are

based on OTAGO and FaME exercises for older people (strength and balance exercises with demonstrated effectiveness to reduce falls) [44–46]. The Exergames draw on self-determination theory and gamification to aid uptake, motivation and adherence to the Exergame programme [40]. Evaluation of this intervention is particularly timely given the current emphasis on healthy ageing and prevention [46, 47]. A cluster randomised trial design was adopted as individual randomisation within assisted living facilities would have been open to contamination bias. The research hypothesis was that a 12-week tailored programme of strength and balance Exergames will improve balance in people aged 55 years and older, in assisted living facilities.

Study objectives

The primary objective of this study was to evaluate the effectiveness of a tailored 12-week fall prevention Exergame programme on balance in adults aged 55 years or older as assessed by the Berg Balance Scale [48].

The secondary objectives were to investigate the effectiveness of the Exergame programme on fear of falling, lower limb function, self-reported physical activity, fall risk, pain, mood, fatigue, cognition, healthcare utilisation, health-related quality of life (HRQoL) and fall rates during a 3-month follow-up.

Methods

Design

This was a multi-centre, cluster randomised (1:1 ratio) controlled trial comparing fall prevention Exergames plus standard care (physiotherapist advice and leaflet) against standard care only in adults aged 55 years or older, dwelling in assisted living facilities (a cluster comprised one facility).

Study setting and participants

Clusters were assisted living facilities (also known as sheltered housing facilities or specialist housing) for people in Greater Manchester or Glasgow, identified via a national housing website [49]. Clusters were eligible if they housed residents aged ≥ 55 years, were willing to take part as agreed by their managers and had sufficient communal space (i.e. $> 10 \text{ m}^2$) to exercise without obstacles. The facilities comprised individual flats and bungalows (ranging from 28 to 80) with residents aged between 45 to 102 years. Each facility had a communal lounge where residents would meet to undertake the intervention. Between January and May 2016, 18 assisted living facilities were invited to participate in geographic areas that included a range of levels of deprivation in urban and semi-urban areas. Eligibility criteria for participants are presented in Table 1.

Managers at the assisted living facilities invited residents to attend an information session about the Exergames and the study, presented by ES or AM. Trained

research staff and research physiotherapists initially identified residents who appeared to meet inclusion criteria, and ascertained if they were willing to receive information about the study, before providing them with participant information sheets and consent forms. After at least 24 h, participants were consented, fully assessed for inclusion as per protocol and underwent physical assessment by a research physiotherapist. All participants' general practitioners (GP) were notified of study participation and eligibility criteria were verified using GP records.

Cluster randomisation and blinding

To reduce the potential for selection bias, baseline assessments took place before randomisation. Cluster randomisation of the units was based on blocks of two in each location (Manchester; Glasgow), matched according to readiness to deliver the intervention, and the number of consented participants per facility. Recruitment was staggered, with Manchester sites recruiting first. Randomisation was computer-generated (using Stata 14) [50] and performed by the Lancashire Clinical Trials Unit (CTU). Clusters were enrolled and assigned by ES and DS. Blinding of the assessors at the 12-week assessment was not possible for two out of the three assessors due to participants revealing the group allocation of their assisted living facility/cluster. Data analysis was performed by two unblinded researchers at the CTU (CJS, VB) based on an a priori statistical analysis plan. Recruitment commenced in Manchester in January 2016 and ended in Glasgow in June 2016, with the final follow-up being completed in November 2016.

Description of the interventions

The Control and Exergame group interventions are summarised in Table 2.

Control

A physiotherapist gave members of the control group standard community fall prevention advice comprising the Age UK Staying Steady leaflet [51] and the OTAGO strength and balance home exercise programme leaflet [52]. Control participants were encouraged to do three preselected (by the physiotherapist) exercises from the OTAGO list over the 12-week period. After 12 weeks, control participants were offered the opportunity to use the Exergame platform to reduce drop out [53].

Exergame intervention

In the intervention group, the same standard care as the control group was given. In addition, Exergames were offered three times a week (under the supervision of a physiotherapist or physiotherapist assistant) for 12 consecutive weeks in the assisted living facility communal

Table 1 Participant eligibility criteria for the study

Inclusion criteria	Exclusion criteria
Aged ≥ 55 years	Acute illness
Mental capacity (assessed by trained healthcare professional) to give informed consent	Severe congestive cardiac failure
Able to speak English sufficiently to understand exercise instructions	Uncontrolled hypertension
Registered with a primary care general practice	Recent fracture or surgery in past 6 months
Able to watch television with or without glasses from 2 m distance	On waiting list to have orthopaedic surgery
Able to use gaming technology safely as assessed by research physiotherapists (i.e. able to stand with support of aids and follow game instructions)	Myocardial infarction or stroke in the past 6 months
	Dependence on wheelchair use
	Severe auditory or visual impairment(s)
	Peripheral neuropathy or other uncontrolled medical conditions likely to compromise the ability to exercise
	Current use of gaming technology to exercise

rooms. Each participant was given a prescribed programme of standardised Exergames that suited the participant's starting level of ability, with tailored progression (e.g. more Exergames within a session, greater challenge, longer duration) over the 12 weeks.

The physiotherapists and physiotherapist assistants were trained for approximately 30 min in the use of the Exergame system. This consisted of being shown the different games and corresponding exercises and how to set up the laptop and Kinect sensor (version 2; Microsoft Corp., Redmond, WA) and set up a programme for users (Fig. 1). The Kinect sensor requires placement 1 m above the ground and can be manually tilted so that it tracks the participant's entire body. The participant needs to face the Kinect sensor, with no obstacles in front or to

the side to allow free movements, and stand at a distance of 2–3 m.

Physiotherapists and assistants familiarised themselves with the system prior to commencing the trial. Remote technical assistance was provided by MIRA Rehab during the trial. The Exergame system used in this trial was designed to engage and motivate individuals to participate in 'game'-driven physical activities [54]. In an earlier feasibility study, this Exergame system showed potential to improve balance and increased engagement through motivational design [35]. The Exergame system enables interaction with the user by giving verbal and subtitled feedback on correct movements and any adjustments that may be required. It utilises the Microsoft Kinect (Microsoft Corp., Redmond, WA), a 3D motion tracking device that does not require handheld controls. This tracks the user's performance and records parameters such as frequency and duration of use. Individual exercise programmes can be tailored using a choice of games for lower or upper limb exercises (see Additional file 1: Tables S1, S2 and Figure S2). The system also supports remote monitoring, whereby the user's exercise programme (and progress) can be remotely viewed and adjusted by a remote supervisor, but this was not evaluated during this study.

Outcome measures

Assessments were completed with individual participants at baseline and 12 weeks by trained physiotherapists and included a series of standardised tests and questionnaires (Table 3).

Balance at 12 weeks post-baseline, measured by the Berg Balance Scale [55], was the primary outcome measure.

A 3-month follow-up of self-reported participant falls (baseline assessment) was conducted using daily fall calendars that were posted monthly to the researchers. Participants who reported a fall during the previous month were contacted by telephone to record details of the fall [56].

The trial protocol is registered on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02634736) reference: NCT02634736.

Sample size

A sample size calculation (5% two-sided significance level, 90% power) to detect a between-group difference in mean clinically important change in the Berg Balance Scale (BBS) of 8 points [68], indicated a sample size of 23 participants in each group was needed. Assuming a common standard deviation (SD) of 8.0 (conservative estimate from a pilot trial) [35], using an independent-samples *t*-test and assuming a conservative intraclass correlation coefficient (ICC) of 0.05 and a cluster size of 9 participants, this leads to a design effect of 1.4 and sample size of 33 per arm. In our pilot study, 22/24 (92%) provided outcome data at week 6. Conservatively, we assumed a 75% retention rate

Table 2 Summary of the control and Exergame group interventions

Description of intervention	Control group	Exergame group
AGE UK Staying Steady Falls Prevention Leaflet [51]	Yes	Yes
OTAGO Strength and Balance Home Exercise Leaflet [52] and advice from physiotherapist to undertake 3 OTAGO-based exercises 3 times per week for 12 weeks	Yes	Yes
Tailored Exergame programme supervised by physiotherapists/physiotherapist assistants 3 times per week for 12 weeks	No	Yes

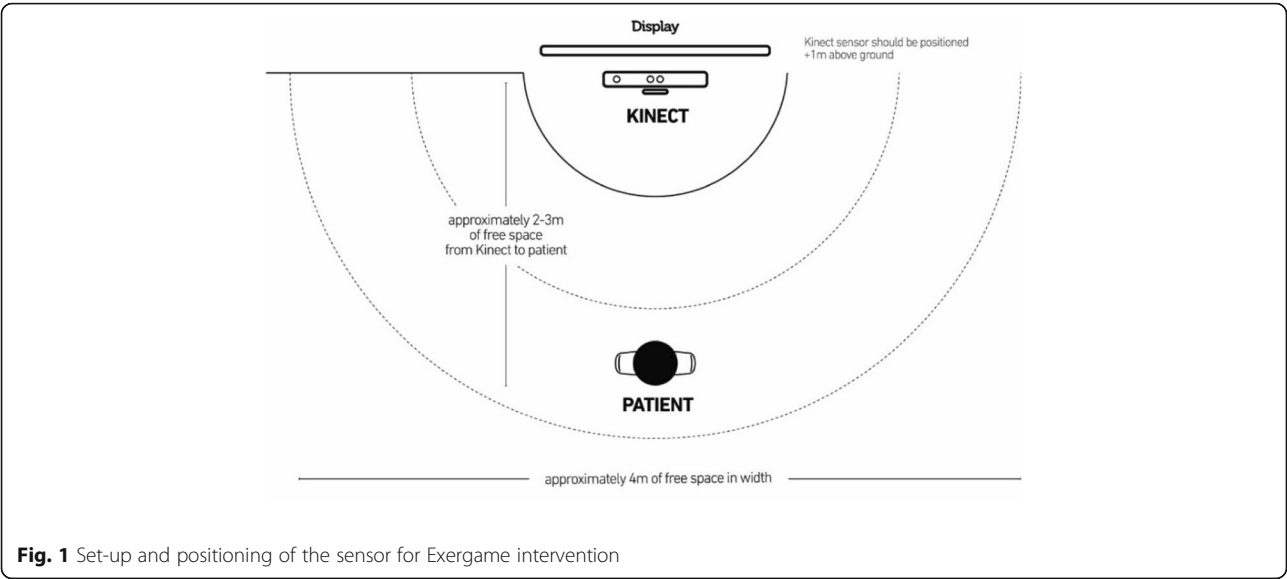


Fig. 1 Set-up and positioning of the sensor for Exergame intervention

at week 12. Therefore, at least 5 assisted living facilities in each arm (a total of 10 assisted living facilities), with a site average of 9 participants recruited, were required. However, to allow for unit attrition or limited participation, we recruited a total of 18 assisted living facilities.

Data collection and analysis

Participant characteristics assessed at baseline included age, sex, ethnicity, employment, marital status, socioeconomic status (Index of multiple deprivation of participants’ assisted living facility postcode), fall history and self-reported vision. Outcome measures (Table 3) were assessed at baseline and 12 weeks.

Statistical analysis

Our primary analysis was intention-to-treat; therefore, we included all participants willing to provide outcome data irrespective of their engagement with the Exergame or control intervention. We implemented this using a complete case analysis, and no imputation of missing outcome data was performed. However, a sensitivity analysis on the primary outcome variable was performed using multiple imputation (using a linear regression model, with age, BBS at baseline, location and group as predictors) [69] if there was more than 10% missing data or a between-group difference of more than 10% in the percentages with missing data. To account for the cluster randomisation, linear mixed effects modelling for the

Table 3 Outcome measures

Primary outcome	Times at which assessed
Berg Balance Scale (BBS) [55]	Baseline, 12 weeks
Secondary outcomes	
Falls (fall diary) [56]	Daily self-report, posted monthly for 3 months
Adherence: frequency, duration, number of sessions [54]	Recorded at each use of Exergame
Timed Up and Go (TUG) [57]	Baseline, 12 weeks
Fall risk score (FRAT) including VAS pain and VAS fatigue [58]	Baseline, 12 weeks
Physical Activity Scale for the Elderly (PASE) [59]	Baseline, 12 weeks
Addenbrooke’s Cognitive Examination III (ACEIII) [60]	Baseline, 12 weeks
Short Falls Efficacy Scale-International (Short FES-I) [61]	Baseline, 12 weeks
Geriatric Depression Scale (5-item GDS) [62]	Baseline, 12 weeks
Health-related quality of life (HRQoL), Euro-QoL EQ-5D-5L [63, 64]	Baseline, 12 weeks
Monetary costs of health care utilisation following falls [65]	Daily self-report calendar, posted monthly for 3 months and follow-up phone calls [56]
Usability and acceptance of Exergames (system usability scale (SUS) [66] and technology assessment model (TAM)) [67]	12 weeks (Exergame group only)

primary and secondary outcomes was used to compare the two groups. The group indicator was included in each outcome model as the focus of the analysis and adjustment was performed for the following variables: assisted living facility unit (random effect), baseline measures of the corresponding outcome variable (fixed effect), location indicator (Manchester; Glasgow; fixed effect). To investigate potential differences in effectiveness between locations, we added a location-by-intervention interaction term to the model for the primary outcome measure.

Fall data were summarised as recommended by ProFaNE [70] using the number of falls, number of non-fallers/single fallers/multiple fallers and fall rate per person-year. We investigated the effect of the Exergame intervention on fall rate by estimating the incidence rate ratio (IRR) using Mantel-Haenszel methods, stratified by match pair [71].

A significance level of 5% was used, and effectiveness estimation included both point and 95% confidence interval estimates. All analyses were performed using Stata 14 [50].

Economic analysis

The primary objective of the economic analysis was to assess the incremental cost-effectiveness of Exergames compared to treatment as usual (TAU). In this case, TAU was a visit from a physiotherapist to explain the Otago Exercise Programme (OEP) and to talk through a leaflet on fall prevention and an additional leaflet explaining the OEP recommended exercises. The control arm was asked to undertake their individually recommended exercises three times a week in their leisure time. However, TAU was not the full OEP (which may be the case in a non-trial setting) that is delivered by trained personnel at home [72] or in group setting [73]. The analysis was conducted alongside the Exergame trial from the perspective of the English National Health Service (NHS).

Quality-adjusted life years (QALYs) were calculated based on EQ-5D-5L using the area under the curve method assuming linear extrapolation of utility between time points. Following Hunter et al., we calculated the QALYs at the individual level (rather than at the group level) [74]. Health care services resource-use data were collected during the study and combined with relevant unit cost data for the financial year 2015–2016 to calculate the total health service costs incurred over the study period.

Multiple-imputation techniques were used for the main analysis presented here. Following White et al. and Faria et al., we used 15 imputations (as the missing data percentage was approximately 15%) [75, 76].

The incremental cost-effectiveness ratio (ICER) was calculated, adjusting for baseline EQ-5D-5L index score

following Manca et al. [77]. We further adjusted for gender and age at baseline as well as identifiers for each of the residential homes.

Results

Study participants

Figure 2 shows the flow of participants through the study. Eighteen assisted living facilities gave permission at a managerial level to take part in the study and were randomised to control ($n = 9$) or to Exergame intervention ($n = 9$). The assisted living facilities ranged from smaller facilities with 19 occupied flats to larger facilities with 80 occupied flats. Following invitation by the managers of the facilities, 137 adults aged 55 years or older expressed an interest in participating in the study. Of these, 31 did not meet the inclusion criteria mostly related to participants not having the mental capacity to consent (Fig. 2). All assisted living facilities randomised were retained in the trial.

The 106 participants' baseline characteristics are presented in Table 4. Almost 80% of the participants were female. Mean ages of control and Exergame groups were similar (77.8 (SD = 10.2) vs 77.9 (SD = 8.9) years respectively), and there was a good balance between the groups in terms of ethnicity, employment and marital status. More participants from the Exergame group reported a fall in the previous year (58%) compared to control (42.9%) and Glasgow had higher index of multiple deprivation scores than Manchester sites, particularly in the Glasgow Exergame group.

Study retention and adherence

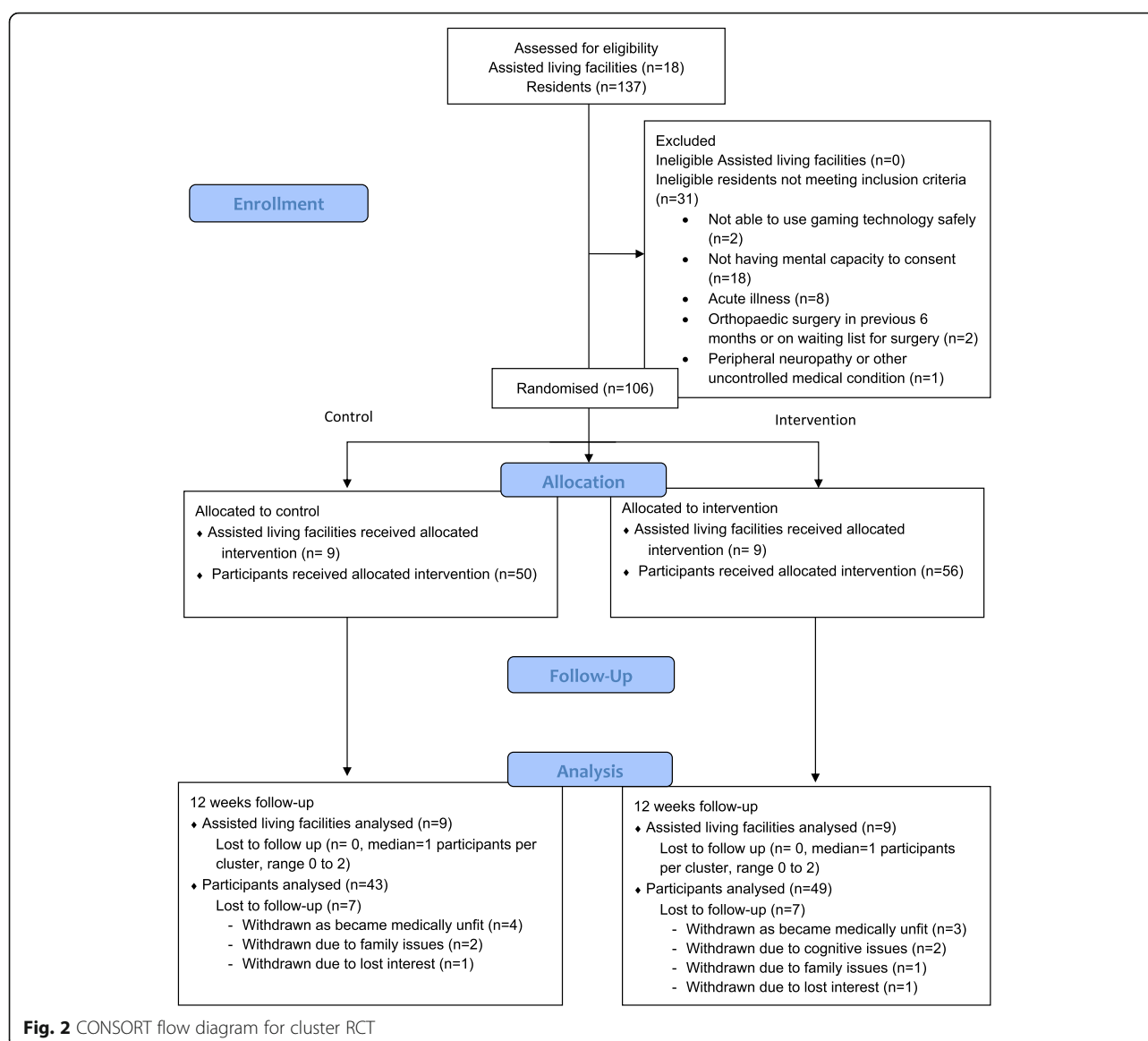
Retention levels at 12 weeks was 86.8%. The most reported reasons for withdrawing from the study were 'being medically (physically/mentally) unfit' ($n = 9$), 'family issues' ($n = 3$) and 'loss of interest' ($n = 2$) (Fig. 2).

The Exergame participants attended a mean number of 25 (SD = 8.5) of a total of 36 sessions offered over the 12-week study period (a mean of 2 out of the 3 weekly offered sessions). Attendance at 12 weeks was 87.5% for the intervention group. The mean Exergame total exercise time at the end of the 12 weeks was 359 min (SD 151.2).

Effect of intervention

Primary outcome

Using ITT analysis, over 12 weeks, the Exergame intervention had a significant positive impact on balance as measured by BBS, relative to control [6.2 (95% CI 2.4 to 10.0; $p = 0.003$)]. The mean positive change of BBS from baseline was 2.9 points (SD 8.5) for the Exergame group, representing a 4.3% improvement from baseline, whilst the control group deteriorated by a mean of 2.8 (SD 6.5) points.



The estimated intraclass correlation coefficient for the BBS at 12 weeks was 0.08. There was no evidence that the effect of Exergames differed between the two locations ($p = 0.39$). As there was more than 10% missing outcome data, a sensitivity analysis was performed using multiple imputation of the missing values of BBS at week 12. Findings were not sensitive to ignoring the missing data and performing a complete case analysis, with the estimated impact of Exergames on BBS at week 12 being almost identical when using multiple imputation (6.2, 95% CI 2.7 to 9.8; $p = 0.002$), thus supporting the ITT results.

Secondary outcomes

Relative to controls, at 12 weeks the Exergames had a positive impact on fear of falling measured by Short

FES-I (adjusted mean difference = -2.7 , 95% CI -4.5 to -0.8 , $p = 0.007$) and VAS pain scale (-12.1 , 95% CI -22.3 to -1.8 , $p = 0.024$). No statistically significant impact of the Exergame intervention was found on any other secondary outcomes (Table 5).

Follow-up fall incidence

A total of 55 falls were self-reported by the 106 participants during the 3-month follow-up. Of these, 38 falls were reported by the control group (12 fallers (24%) of whom 5 were single fallers and 7 were multiple fallers), an incident rate of 3.11 falls per person-year. Seventeen falls were self-reported by the Exergame group (11 fallers (20%) of whom 8 were single fallers and 3 multiple fallers), an incident rate of 1.26 falls per person-year. The incident

Table 4 Baseline characteristics

Assistive living facility (ALF) characteristics	Control 'usual care' <i>n</i> = 9	Intervention 'Exergames' <i>n</i> = 9
Location, <i>n</i>		
Manchester	6	6
Glasgow	3	3
Manchester IMD rank ^a , median (range, IQR)	14,844 (3319–23,972, (8839.0–18,169.25))	19,931 (4647–26,933) (11,715.8–26,543.0)
Glasgow SIMD rank ^b , median (range, IQR)	2788 (1382–5907) (2085.0–4347.5)	1004 (149–5100) (576.0–3052.0)
Manchester IMD decile, median (range, IQR)	5 (2–9)	6.5 (2–9)
Glasgow SIMD decile, median (range, IQR)	4 (2–4)	2 (1–8)
Participant characteristics	Control 'usual care' <i>n</i> = 50	Intervention 'Exergames' <i>n</i> = 56
Participants, <i>n</i>	50	56
Manchester	32	41
Glasgow	18	15
Female sex, <i>n</i> (%)	38 (76.0)	45 (80.4)
Age, years (SD/range)	77.8 (10.2/58–101)	77.9 (8.9/58–96)
Ethnicity, <i>n</i> (%)		
White British or Irish	50 (100)	52 (92.9)
Asian or Asian British	0 (0.0)	1 (1.8)
Mixed	0 (0.0)	2 (3.6)
Other ethnic groups	0 (0.0)	1 (1.8)
Employment, <i>n</i> (%)		
Retired	47 (94.0)	54 (96.4)
Doing voluntary work	1 (2.0)	1 (1.8)
Unemployed through sickness/disability	2 (4.0)	1 (1.8)
Marital status, <i>n</i> (%)		
Single, never married	7 (14.0)	10 (17.9)
Married/living with partner	8 (16.0)	2 (3.6)
Divorced	6 (12.0)	10 (17.9)
Separated	1 (2.0)	1 (1.8)
Widowed	28 (56.0)	33 (58.9)
1 year history of falls, <i>n</i> (%)		
No falls reported (non-fallers)	21 (42)	32 (57)
1 fall reported (single fallers)	14 (28)	7 (13)
> 1 fall reported (multiple fallers)	15 (30)	17 (30)
Self-reported vision, <i>n</i> (%)		
Excellent	4 (8)	7 (13)
Good	24 (48)	22 (39)
Fair	16 (32)	19 (34)

Table 4 Baseline characteristics (Continued)

Poor	5 (10)	7 (13)
Very poor	1 (2)	0 (0)
Registered blind	0 (0)	1 (2)

IMD and SIMD decile score ranges 1–10, where 1 is the least deprived and 10 the most deprived

^aThe IMD (2015) rank is the Index of Multiple Deprivation and combines a number of indicators, chosen to cover a range of social, economic and housing issues, into a single deprivation ranked score, the lower the score the more deprived

^bThe SIMD (2016) rank is the Scottish equivalent of the IMD rank

rate ratio (IRR) of falls between groups was 0.31 (95% CI 0.16 to 0.62, *p* = 0.001) in favour of Exergames.

Health economic outcomes

Exergames were associated with a mean incremental total cost increase of £101.84 (95% CI –£7.42 to £211.11) and a mean incremental QALY gain of 0.007 (95% CI –0.003 to 0.016) (Table 6). Whilst there were no statistically significant differences in costs or QALYs between the control and treatment arms during bootstrapping, the point estimate of the ICER was £15,209.80 per QALY.

The cost-effectiveness plane (Fig. 3) plots the 10,000 bootstrap replications of incremental cost and QALY estimates, to help illustrate the uncertainty surrounding the point estimates in probabilistic terms. The replications were clustered predominantly in the north-east quadrant, reflecting the point estimates that Exergames resulted in a positive health gain, but at an increased cost. Exergames resulted in an incremental QALY gain in 91.5% (9151 out of 10,000) of bootstrap replications, and a higher cost than controls in 95% (9490 out of 10,000) of replications.

The cost-effectiveness acceptability curve (CEAC; Fig. 4) demonstrates how the probability that Exergames are cost-effective increases with the decision-maker's willingness to pay. At the lower bound of the NICE threshold [78] of £20,000 per QALY, there was a 61% probability of Exergames being cost-effective. This rose to 73% at the upper bound of £30,000. Compared with controls, Exergames were likely to be cost-effective in 50% or more cases if decision makers are willing to pay approximately £15,500 for one additional QALY.

Exergame usability and acceptance

Participants scored the Exergame system (set up by the physiotherapist or assistant) on the technology assessment model (1 = strongly disagree to 7 = strongly agree) as easy to use (mean = 6.3, SD = 1.4) and useful (mean = 5.9, SD = 1.9). Participants had a favourable attitude (mean = 6.6, SD = 1.2) and indicated they intended to use the Exergame system in the future if it were to become available (mean = 5.7, SD = 2.2).

Table 5 Primary and secondary outcome measures at baseline and 12 weeks

	Baseline (N = 106)	12 weeks (N = 91)	Adjusted difference*	95% CI	p	ICC
BBS (0–56) [SD]			6.18	2.38, 9.97	0.003	0.08
Control	40.6 [13.1]	37.6 [14.9]				
Exergames	42.0 [13.5]	44.6 [10.7]				
ACE III (0–100) [SD]			− 0.83	− 4.10, 2.45	0.60	< 0.001
Control	73.5 [12.1]	80.2 [12.9]				
Exergames	77.4 [15.6]	81.4 (14.2)				
7-item FES-I (7–28) [SD]			− 2.69	− 4.52, − 0.85	0.007	0.12
Control	11.6 [4.5]	12.8 [4.8]				
Exergames	11.0 [4.2]	9.8 [3.4]				
VAS pain scale (0–100) [%]			− 12.07	− 22.31, − 1.83	0.024	< 0.001
Control	24.3 [26.5]	34.4 [30.5]				
Exergames	23.9 (25.9)	21.9 [27.7]				
VAS fatigue scale (%)			− 6.63	− 20.58, 7.32	0.33	0.10
Control	32.4 [26.6]	39.2 [28.0]				
Exergames	37.5 [31.2]	34.6 [31.3]				
FRAT (0–5) [SD]			− 0.15	− 0.55, 0.26	0.46	0.05
Control	2.4 [1.3]	2.4 [1.4]				
Exergames	2.3 [1.1]	2.2 [1.2]				
5-item GDS (0–5) [SD]			0.21	− 0.24, 0.65	0.34	0.04
Control	1.4 [1.3]	0.98 [1.1]				
Exergames	1.2 [1.3]	1.0 [1.3]				
TUG (s) [SD]			− 0.82	− 3.62 to 1.98	0.54	< 0.001
Control	20.4 [14.3]	20.7 [13.3]				
	17.5	17.8				

Table 5 Primary and secondary outcome measures at baseline and 12 weeks (Continued)

	Baseline (N = 106)	12 weeks (N = 91)	Adjusted difference*	95% CI	p	ICC
Exergames	[9.0]	[10.4]				
EQ5D5L-VAS (0–100) [SD]			3.86	− 6.46 to 14.17	0.44	0.05
Control	71.2 [18.3]	67.2 [22.7]				
Exergames	71.2 [21.4]	70.6 [21.1]				
PASE score (0–400) [SD]			− 0.97	− 19.54 to 17.60	0.91	0.10
Control	66.8 [38.2]	72.3 [41.5]				
Exergames	75.1 [50.5]	77.5 [43.1]				

Unless otherwise stated, means (SD) are reported

BBS Berg Balance Scale, SD standard deviation, ACE III Addenbrooke's Cognitive Examination–III, 7-Item FES-I 7-Item Falls Efficacy Scale-International, VAS visual analogue scale, FRAT Falls Risk Assessment Tool, GDS Geriatric Depression Scale, TUG Timed Up and Go, EQ5D5L-VAS European Quality of Life 5

Dimensions -Visual Analogue Scale, PASE Physical Activity Scale for the Elderly

*Outcome (e.g. BBS) at 12 weeks adjusted for baseline value of outcome measure, region (Manchester/Glasgow) and site (random effect)

The mean system usability scale (range 0–100) at 12-week assessment was 82.4 (SD = 15.5) indicating high usability [79].

No major protocol deviations or unexpected adverse events occurred during the study period.

Discussion

This is the first cluster RCT of Exergames in community-based, assisted living facilities. Provision of Exergames for strength and balance exercises over 12 weeks to residents aged 55 years and older of these facilities significantly improved balance (as measured by the BBS), pain (VAS) and fear of falling (Short FES-I). Furthermore, an IRR = 0.31 for falls over a 3-month follow-up indicates an unexpected significant effect for this fall reduction.

The trial was powered on the minimum detectable change (MDC) of 8 points on the BBS from a trial of dependent older people (living in residential care homes) of somewhat older age than those in this trial [68]. However, other studies have found that the MDC for more physically independent older people receiving physiotherapy was rather less (3.2 points [80] and 4.9 points [81]). Furthermore, it has recently been advised that studies should not be powered on distribution-based statistics, such as the MDC [82], but should primarily use anchor-based methods and/or expert opinion to estimate the minimally important difference (MID).

Table 6 Cost-effectiveness analysis comparing Exergames with OEP leaflet control

	Coeff.	Bootstrapped standard error	Bootstrapped 95% confidence interval
Incremental cost (£)	101.84	55.75	[− 7.42 to 211.11]
Incremental QALYs	0.007	0.004	[− 0.003 to 0.016]
ICER (£)	15,209.80		

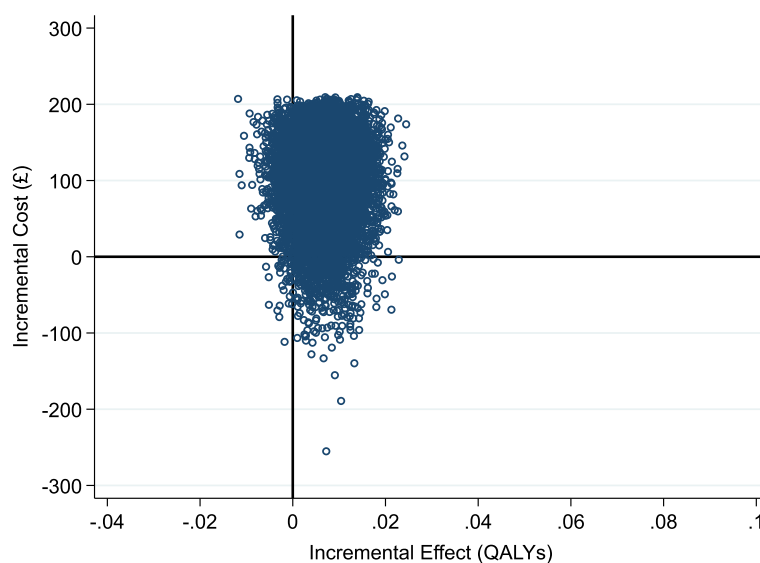
Bootstrapping based on 10,000 replications. Note the ICER is not exactly equal to the ratio due to rounding

There has been no research to determine the MID for the BBS on a population similar to ours, but Saso et al. [81] found an MID of 6 points for people early after stroke and Godi et al. [83] found an MID of 7 points for a groups of older people with balance deficits undergoing rehabilitation. Given the nature of the population in our trial, the MID would be expected to be not greater than 6 and perhaps a little smaller. The estimated difference in change between the groups for balance (BBS 6.2 points) is therefore plausible as an important difference, if only slightly exceeding the likely MID. However, the 95% confidence interval for this effect is relatively wide (2.4 to 10.0) so further research is recommended to provide further evidence as to the magnitude of the effect.

The results of our economic evaluation imply that Exergames are likely to be cost-effective compared to control (physio advice and the Otago Exercise Programme leaflet). These findings were robust, controlling for baseline characteristics using multiple imputation or complete case analysis, and choice of methodology to derive utility values from the EQ-5D-5L instrument. In the primary analysis, the ICER was £15,209.80 per QALY, and there was a 61–73% probability of Exergames being cost-effective at NICE thresholds [78] of £20,000–£30,000 per QALY. It should be noted that the full Otago Exercise Programme consists of a set of three

times per week progressive exercises, over a 12-month period and a walking plan with multiple home visits by an instructor [45]. Therefore, traditional Otago Exercise Programme costs would be much higher than those proposed in this current 12-week study due to the additional labour costs, on-going training, travel, telephone calls and overhead costs.

This study demonstrated consistent findings between the locations indicating the potential transferability of the Exergame system. Retention of the Exergame participants was high (87%) compared to other exercise programmes for older people [84], with a mean attendance at Exergame sessions of around two thirds (69%). Although there is no current consensus on the cut-off points for levels of high, moderate or low adherence [85], this may be considered a beneficial level of attendance that resulted in improvements in balance, the primary outcome measure and also falls. Participants also reportedly liked the Exergames and found them easy to use (albeit, after it had been set up by the therapists, so this may refer to their understanding and playing of the Exergames). These are important factors when considering not just the effectiveness of the intervention but also whether people will actually want to use it in the long term [86]. We recorded no adverse events related to the 12-week intervention.


Fig. 3 Cost-effectiveness plane for Exergames vs OEP leaflet control

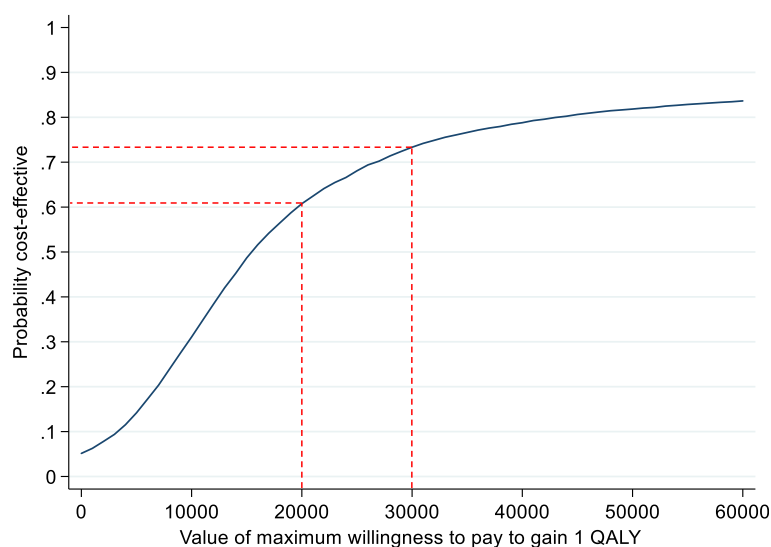


Fig. 4 Cost-effectiveness acceptability curve of willingness to pay for one additional quality-adjusted life year (£)

Strengths and limitations

Baseline assessment was undertaken pre-randomisation, thus limiting the potential for selection bias. Sample sizes were achieved and high retention rates suggest little effect of attrition bias. Recruitment across multiple locations provides some evidence of generalisability across assisted living facilities and should reduce risks of performance bias. The Exergames were tested with people aged 55 years or older using rigorous methods in a 'real-world' context in communal areas in assisted living facilities rather than in a controlled laboratory-type setting, and the physiotherapists and assistants had no prior experience of this type of technology. Benefits of the intervention were that the Exergames were co-designed with older people and therapists and are based on evidence-based exercises (FaME and OTAGO) and gamification health psychology [27] and can be tailored to a participant's level of ability, preference and progression (i.e. different upper and lower limb exercises could be matched to different games and changed throughout the intervention period to maintain interest).

Cluster randomisation was essential to ensure that intervention contamination did not occur, but this also made blinding of the assessors difficult. Therefore, despite the use of objective measures and standardised participant instructions, it is possible that some of the improvements at follow up may have resulted from detection bias and so the results should be interpreted with caution. Blinding of the data analysts would also have been difficult, although there is sparse evidence that this may have affected outcomes [87]. An a priori analysis plan was agreed and executed to minimise risk of reporting bias.

The incidence rate ratio for falls over the 3-month follow up (IRR = 0.31) significantly favours the Exergame

group and this is in line with community-based RCTs testing the exercises that the Exergames were based on [3, 9, 52]. But falls were only followed up for 3 months, and falls were self-reported by the participants. Recall bias could be present, and it is recommended in future studies that falls are prospectively followed up for 1 year as per the ProFaNE consensus guidelines [70]. A further limitation is that the majority of the participants were women and of white, British ethnic origin. Future studies need to target ethnic groups and more men. Changes in physiotherapy staffing (one change in Manchester, two changes in Glasgow) could have also affected the delivery of the intervention, as it was observed that it took around 2 weeks for the therapists to become confident in setting up and delivering the Exergames to the intervention group. There tended to be more remote technology support required during these early weeks to ensure the sessions ran smoothly. These support issues caused short delays in the delivery of the Exergames which could have reduced both the duration of the session and the enjoyment level of the participants.

Attendance at the Exergame sessions was generally good, but the amount of time spent exercising (mean 33 min per week) was well below the recommended level of 150 min per week of moderate aerobic activity for adults and older people [46]. This appears to be an issue, even in well-designed community exercise RCTs [88]. However, in one recent cluster RCT, increased levels of physical activity were self-reported, albeit below the recommended levels, and the fall rate was reduced [89].

Future studies are needed to investigate the optimum intensity, progression and long-term adherence to Exergame programmes. Moreover, such studies should investigate improvements in balance using clinical measures

(e.g. BBS) with also include an instrumental measurement of static and dynamic balance (e.g. posturography) and include other outcomes such as lower limb muscle strength [14], fall rates, fall risk, fatigue and habitual physical activity. In particular, a definitive trial is recommended to evaluate the cost-effectiveness of the implementation of the Exergames with a primary outcome of fall rates, and costs per QALY along with a process evaluation comparing traditional delivery of exercise [86]. More research is also required to test the effectiveness of Exergames in other settings such as care homes, within early hospital discharge schemes, or to top-up or continue longer-term rehabilitation at home under remote monitoring by clinicians. This is particularly important as, in frailer older adults, unsupervised home exercise may be risky [19].

Conclusions

The use of technology to reduce falls and to support exercise uptake and adherence in younger and older adults is increasing. This study has demonstrated that an evidence-based programme of Exergames is an acceptable, effective and potentially cost-effective way to improve balance, pain and fear of falling. Exergames may be a scalable intervention to reduce falls (at a personal and societal level).

Additional file

Additional file 1: Table S1. Exercise description and corresponding games. **Figure S1.** An example of a participant Exergame schedule. **Table S2.** Games and description of play. (DOCX 876 kb)

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Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

All authors meet the requirements for authorship. ES led the conception, design and application for funding of the project in conjunction with CT, CS and DS. VBel, WM, AM and LDdJ were study site investigators. ES led the drafting of all sections of this manuscript except the results in consultation with all of the co-authors. CS and VBen were responsible for the analysis and interpretation of data. LM was responsible for the economic evaluation. All authors reviewed and revised

the manuscript critically for important intellectual content. ES is the guarantor. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This research complies with the Declaration of Helsinki. Ethics approvals for this study were obtained from London - Camden & Kings Cross Research Ethics Committee, UK, reference number 16/LO/0200. All participants provided written informed consent prior to entering the study. The trial was registered at ClinicalTrials.gov on 18 Dec 2015 with reference number NCT02634736.

Consent for publication

Not applicable.

Competing interests

Dawn Skelton is a Director of Later Life Training, a not for profit training company that provides training in delivery of the Otago and FaME Programmes with the UK, Europe and Singapore. No other conflicts of interest are declared.

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Author details

¹Division of Nursing, Midwifery and Social Work, School of Health Sciences, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester M13 9PL, UK. ²Manchester Academic Health Science Centre, Core Technology Facility, The University of Manchester, 46 Grafton Street, Manchester M13 9NT, UK. ³Manchester University NHS Foundation Trust, Manchester, UK. ⁴School of Health and Life Sciences, Centre for Living, Glasgow Caledonian University, Govan Mbeki Building, Cowcaddens Road, Glasgow G4 0BA, UK. ⁵School of Physiotherapy and Exercise Science, Faculty of Health Sciences, Curtin University, Perth, Australia. ⁶Centre for Biostatistics, Division of Population Health, Health Services Research & Primary Care, School of Health Sciences, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester M13 9PL, UK. ⁷Lancashire Clinical Trials Unit and Research Support Team, Faculty of Health and Wellbeing, Brook Building, University of Central Lancashire, Preston PR1 2HE, UK. ⁸Manchester Centre for Health Economics, School of Health Sciences, Jean McFarlane Building, University of Manchester, Oxford Road, Manchester M13 9PL, UK. ⁹Tranzo, Tilburg School of Social and Behavioural Science, University of Tilburg, 5000 LE Tilburg, The Netherlands. ¹⁰School of Psychological Sciences & Health University of Strathclyde Graham Hills Building, Glasgow G1 1QE, UK.

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